

Application No.: 10/074,272

Amendment and Response dated November 17, 2005

Reply to Office Action of October 3, 2005

Docket No.: 1199-4 RCE

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**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claims 1-53 (cancelled)

Claim 54 (withdrawn): A process for making a film having a substantially uniform distribution of components comprising:

- (a) combining a water-soluble polymer component and polar solvent to form a matrix with a uniform distribution of said components;
- (b) forming a film from said matrix by feeding said film onto a surface having top and bottom sides; and
- (c) drying said film said bottom side of said surface being in substantially uniform contact with a water bath at a temperature sufficient to dry said film.

Claim 55 (withdrawn): The process of claim 54, wherein said water bath is temperature controlled.

Claims 56-61 (cancelled)

Claim 62 (withdrawn): The process of claim 54, further comprising the step of adding an active component to said matrix of step (a).

Claim 63 (withdrawn): The process of claim 54, wherein said film is ingestible.

Claim 64 (withdrawn): The process of claim 54, wherein said drying step maintains a non-self-aggregating uniform heterogeneity of said components throughout said film.

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Claim 65 (withdrawn): The process of claim 54, wherein said film is flexible when dried.

Claim 66 (withdrawn): The process of claim 54, wherein said film is self-supporting.

Claim 67 (withdrawn): The process of claim 62, wherein uniform distribution determines the amount of active material component per area.

Claim 68 (withdrawn): The process of claim 62, wherein a specific amount of the active material component may be obtained from said film by cutting said film to a predetermined size.

Claim 69 (withdrawn): The process of claim 54, wherein said drying of said film occurs within about 10 minutes or fewer.

Claim 70 (withdrawn): The process of claim 54, wherein said film includes a top side and a bottom side and said drying includes drying said bottom side first.

Claim 71 (withdrawn): The process of claim 70, wherein said drying includes applying heat to said bottom side.

Claim 72 (withdrawn): The process of claim 54, wherein said polar solvent is a combination of water and a polar organic solvent.

Claim 73 (withdrawn): The process of claim 54, wherein said polar solvent is water.

Claim 74 (withdrawn): The process of claim 54, wherein said polar solvent added in step (a) has a weight percent of at least about 30%.

Claim 75 (withdrawn): The process of claim 54, wherein said drying of said film reduces the weight percent of said polar solvent to about 10% or less.

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Claim 76 (withdrawn): The process of claim 54, wherein said drying of said film reduces the weight percent of said polar solvent to about 8% or less.

Claim 77 (withdrawn): The process of claim 54, wherein said drying of said film reduces the weight percent of said polar solvent to about 6% or less.

Claim 78 (withdrawn): The process of claim 62, wherein said active component is a member selected from the group consisting of medicaments, flavors, fragrances, enzymes, preservatives, sweetening agents, colorants, spices, vitamins, and combinations thereof.

Claim 79 (cancelled)

Claim 80 (withdrawn): The process of claim 54, wherein said polymer is a cellulose derivative.

Claim 81 (withdrawn): The process of claim 54, wherein said water soluble polymer is a member selected from the group consisting of hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinylpyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol, xanthan gum, tragacanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl copolymers, starch and combinations thereof.

Claim 82 (cancelled)

Claim 83 (withdrawn): The process of claim 54, wherein said film has a thickness of greater than about 0.1 mils.

Claim 84 (withdrawn): The process of claim 54, wherein said film has a thickness of about 10 mils or fewer.

Claim 85 (withdrawn): The process of claim 54, wherein said film has a substantially uniform thickness.

Claim 86 (withdrawn): The process of claim 62, wherein said film is divided into dosage forms of substantially equal dimensions.

Claim 87 (withdrawn): The process of claim 86, wherein each of said dosage forms contains a substantially equal amount of said active component.

Claim 88 (withdrawn): The process of claim 86, wherein said dosage forms contain an amount of said active that varies about 10% or less among said dosage forms.

Claim 89 (withdrawn): The process of claim 54, wherein said drying step comprises forming a visco-elastic structure.

Claim 90 (withdrawn): The process of claim 54, wherein said drying step achieves a film of substantially uniform thickness and component distribution.

Claim 91 (currently amended): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) ~~combining~~ mixing an edible water-soluble polymer component, water and an active component ~~and a polar solvent~~ to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by slow mixing;

(c)(b) forming a wet film from said deaerated matrix;

(d)(c) providing a surface having top and bottom sides;

(e)(d) feeding said film onto said top side of said surface; ~~and~~

(f)(e) ~~forming a self-supporting edible~~ rapidly forming a visco-elastic film by applying hot air currents to said bottom side of said surface with substantially no top air flow to ~~dry said film~~ prevent flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(g) drying said visco-elastic film to form a self-supporting edible film.

Claim 92 (cancelled)

Claim 93 (previously presented): The process according to claim ~~92~~91, wherein said active component is taste masked.

Claim 94 (previously presented): The process according to claim 91, wherein said wet film has a thickness of at least about 30 $\mu$ m.

Claim 95 (previously presented): The process according to claim 91, wherein said wet film has a thickness of at least about 500 $\mu$ m.

Claim 96 (previously presented): The process according to claim 91, wherein said wet film has a viscosity of about 400 cps to about 100,000 cps.

Claim 97 (previously presented): The process according to claim 91, further comprising the step of removing said self-supporting film from said surface.

Claim 98 (previously presented): The process according to claim 97, further comprising the step of dividing said self-supporting film into individual dosage forms of substantially equal dimensions.

Claim 99 (previously presented): The process according to claim 98, further comprising the step of packaging each of said individual dosage forms.

Claim 100 (previously presented): The process according to claim 91, wherein said self-supporting film is formed in conjunction with a removable backing.

Claim 101 (currently amended): A process for making a self-supporting, edible film dosage unit having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component and ~~a polar solvent~~ water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by controlling the mixing speed to prevent cavitation of the matrix in a manner which pulls air into the matrix;

(c)(b) forming a wet film from said deaerated wet matrix;

(d)(c) ~~forming a self-supporting edible~~ rapidly forming a visco-elastic film by applying hot air currents to said film to dry said film to prevent flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(e) drying said visco-elastic film to form a self-supporting edible film; and

(f)(d) dividing said self-supporting film into dosage forms of substantially equal dimensions, wherein each of said dosage forms is compositionally equal.

Claim 102 (previously presented): The process according to claim 101, wherein each of said dosage forms has substantially the same mass.

Claim 103 (previously presented): The process according to claim 101, wherein each of said dosage forms has substantially the same thickness.

Claim 104 (currently amended): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component selected from the group consisting of pharmaceutical actives, cosmetic actives and combinations thereof and a ~~polar solvent~~ water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by controlling the mixing speed to prevent cavitation of the matrix, thereby reducing formation of air bubbles;

(c)(b) forming a wet film from said deaerated wet matrix, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; ~~and~~

(d)(c) ~~forming a self-supporting edible~~ rapidly forming a visco-elastic film by applying hot air currents to said film to dry said film to prevent flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(e) drying said visco-elastic film to form a self-supporting edible film, said dried film having a uniform distribution of said polymer and said solvent components, a uniform weight and a uniform thickness.

Claim 105 (cancelled)

Claim 106 (currently amended): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component and a ~~polar solvent~~ water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by slow mixing;

(c)(b) forming a wet film from said deaerated wet matrix within a time period before the active degrades, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; ~~and~~

~~(d)(e) forming a self-supporting edible~~ rapidly forming a visco-elastic film by applying hot air currents to said film to initiate drying of the depth of said film prior to forming a polymer skin on said top surface of said film and to prevent flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(e) drying said visco-elastic film to form a self-supporting edible film, said dried film having a uniform distribution of said polymer and said solvent components, a uniform weight and a uniform thickness.

Claim 107 (cancelled)

Claim 108 (currently amended): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component and ~~a polar solvent~~ water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by controlling the mixing speed at a sufficiently slow speed to reduce formation of air bubbles;

~~(c)(b)~~ forming a wet edible film from said deaerated wet matrix, said film having a top surface and a bottom surface; and

~~(d)(e) drying said film until said film is self-supporting~~ rapidly forming a visco-elastic film by applying hot air currents to said film, wherein said air currents are applied to said bottom surface of said film at a velocity greater than to said top surface of said film to prevent flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(e) drying said visco-elastic film to form a self-supporting edible film.



Claim 109 (previously presented): The process according to claim 108, wherein said air currents applied to said top surface of said film are less than that which cause surface rippling or skinning prior to drying of the depth of said film.

Claim 110 (currently amended): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, ~~an~~ pharmaceutical active component and ~~a polar solvent~~ water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by slow mixing;

(c)(b) forming a wet edible film from said deaerated wet matrix, said film having a top surface, a bottom surface and a depth of at least about 500 $\mu$ m between said top and bottom surfaces; ~~and~~

(d)(e) ~~drying said film until said film is self-supporting~~ rapidly forming a visco-elastic film by applying hot air currents to said film, wherein said air currents are less than that which cause surface rippling or skinning prior to drying of the depth of said film, to prevent flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(e) drying said visco-elastic film to form a self-supporting edible film.

Claim 111 (currently amended): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component and ~~a polar solvent~~ water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by slow mixing;

~~(c)(b)~~ forming a wet edible film from said deaerated wet matrix, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; and

~~(d)(e)~~ ~~drying said rapidly forming a visco-elastic film~~ by applying hot air currents to said film to prevent flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(e) drying said visco-elastic film, wherein said dried film is self-supporting and said top surface of said dried film is non-rippled.

Claim 112 (currently amended): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) combining and mixing an edible water-soluble polymer component, an active component and ~~a polar solvent~~ water to form an edible matrix with a compositionally uniform distribution of said components, ~~wherein the mixing speed is controlled to reduce formation of air bubbles;~~

(b) deaerating said matrix by controlling the mixing speed to reduce air bubble inclusions and applying a vacuum;

~~(c)(b)~~ forming an edible film from said deaerated matrix, said film having a top surface and a bottom surface; ~~and~~

~~(d)(e)~~ drying said film from said bottom surface to said top surface by applying hot air currents to said bottom surface of said film until ~~said film is self-supporting~~ a visco-elastic film is achieved; and

(e) further drying said visco-elastic film to form a self-supporting edible film.

Claim 113 (cancelled)

Claim 114 (currently amended): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component and ~~a polar~~

~~solvent~~ water to form an edible matrix with a compositionally uniform distribution of components;

(b) deaerating said matrix by slow mixing;

(c)(b) forming a wet edible film from said ~~deaerated~~ wet matrix, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; and

(d)(e) ~~drying said~~ rapidly forming a visco-elastic film until said film is self-supporting  
by applying hot air currents to said film, wherein said air currents are insufficient to cause one or more of the following:

(i) surface skinning prior to drying the depth of said film;

(ii) surface rippling;

(iii) self-aggregation of components;

(iv) non-uniformity in the thickness of said film; and

(v) non-uniformity of mass per unit volume; and

(e) drying said visco-elastic film to form a self-supporting edible film.

Claim 115 (cancelled)

Claim 116 (currently amended): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) combining and mixing an edible water-soluble polymer component, an edible active component and ~~a polar solvent~~ water to form an edible matrix with a compositionally uniform distribution of components;

(b) adding an anti-foaming agent to release oxygen from said mixture of components;

(c) further deaerating said matrix by slow mixing;

(d)(e) forming a wet edible film from said ~~mixture of components~~ deaerated matrix;

(e)(e) providing a surface having top and bottom sides;

(f)(d) feeding said wet film onto said top side of said surface; and

(g)(e) ~~forming a dried, self-supporting edible~~ rapidly forming a visco-elastic film having a uniform distribution of components by directing hot air currents at said bottom side of said

surface to prevent air flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(h) drying said visco-elastic film to form a self-supporting edible film.

Claim 117 (currently amended): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) ~~combining~~ forming a masterbatch premix of an edible water-soluble polymer component and water a polar solvent to form an edible matrix with a uniform distribution of said components;

(b) deaerating said premix by slow mixing;

(c) feeding a predetermined amount of said deaerated premix to at least one mixer;

(d) adding an active component to said at least one mixer;

(e) mixing said active component and said predetermined amount of said premix to form a matrix having a uniform distribution of components;

(f)(b) forming a wet film from said matrix;

(g)(e) providing a surface having top and bottom sides;

(h)(d) feeding said film onto said top side of said surface;

(i)(e) ~~forming a self-supporting edible~~ rapidly forming a visco-elastic film by applying hot air currents to said bottom side of said surface with substantially no top air flow to dry said film to prevent air flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(j) drying said visco-elastic film to form a self-supporting edible film; and

(k)(f) removing said self-supporting film from said surface.

Claim 118 (cancelled)

Claim 119 (currently amended): A process for making a film having a substantially uniform distribution of components comprising:

- (a) combining a water-soluble polymer component, an active component and ~~polar solvent~~ water to form a matrix with a compositionally uniform distribution of said components;
- (b) deaerating said matrix by slow mixing;
- (c)(b) forming a film from said deaerated matrix;
- (d)(e) providing a surface having top and bottom sides;
- (e)(d) feeding said film onto said top side of said surface; ~~and~~
- (f)(e) ~~drying said~~ rapidly forming a visco-elastic film by applying heat to said bottom side of said surface to prevent air flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and
- (g) drying said visco-elastic film to form a self-supporting edible film.